

### **REMARKS**

This Amendment Reply is a complete response to all of the outstanding objections and rejections. It is anticipated that the present claim amendments and remarks should place this case in condition for allowance.

By the present amendments, the apparatus claims 1-2 have been amended to bring them more in accordance with US practice. For example previous “and/or” and “characterized in that” phraseology is removed as is the reference to Figure numbers.

Claims 4-14 have been amended to more clearly define the invention. In particular these claims are amended to delete reference to Figure number designations as suggested by the Examiner.

Method claims 15-17 have been cancelled in favor of new claims 30-35. Essentially, Original claim 15 has been rewritten as two independent claims 30 and 33 (with dependent claims 31-32 and 34 and 35 being essentially the same as claims 16-17). These new claims are in addition supported by the original claims and find sufficient basis in the earlier claims, and the application as filed.

Further, new claims 18-29 are added which substantially correspond to the original claims but are directed to additional embodiments of the invention which are supported by the original specification and figures.. These amendments and claim additions do not introduce any new matter into the specification.

The specific objections and rejections contained in the Office Action are separately addressed below.

#### **Antecedent Basis Objection to the Specification**

The specification stands objected to as lacking proper antecedent basis for the value of 0.5 ohms for the specified threshold value for detected impedance values recited in claims 3 and 9.

This rejection is respectfully traversed. The application as originally filed included the claims which made reference to the specified 0.5 Ohm threshold level for the detected impedance values.( claim 3 and 9). As the original claims constitute part of the specification it is submitted that this antecedent basis objection should be vacated.

In addition, it is noted that the impedance threshold level between correct and incorrect placement of the endo-tracheal tube of 0.5 Ohms finds implicit support from Figure 2 and 3 based upon the peak-valley variation will be equal to the difference of 0.5 Ohms.

However, if the Examiner so requests the specification will be amended to include explicit reference to the use of 0.5 ohms as a specified threshold level for the detected impedance values.

### **Claim Objections**

Claims 1-2, 4-9, stand objected to as containing reference characters in parentheses contained in the Figures. The Examiner indicates that these numbers are not accorded any patentable weight. This objection should be moot as the claims are amended herein to delete all of these Reference numbers.

Withdrawal of this objection is respectfully solicited.

### **§112 Rejection of Claims 6-17**

These claims stand rejected based on the wording of original claim 6 which contains reference to a first impedance measurement assertedly without making clear how there would be no impedance value. It is believed that this rejection is overcome based on the present amendment of claim 6 and others which now refer to a “specified” threshold value which is used as a standard to detect whether the intubation tube is properly or improperly oriented in a recipient. It is therefore believed that the amended claims overcome the §112 rejection. (It is also noted that claim 6 as written finds support at least in paragraphs 50-51 of the specification.)

The objection as to claim 15 is moot as this claim is cancelled and the objection (of incompleteness) is not applicable to new claims 30-35.

### **§103 Rejections of Claims**

Claims 1-2, 4-5, 10-11 and 14-17 stand rejected under 35 USC 103 as assertedly being obvious over the combined teachings of Wodicka et al., US Patent No. 5,445,144 and Pross et al., US Patent No. 4,449,537 . This rejection is respectfully traversed to the extent it may be applicable to the claims as amended or newly presented.

The Wodicka reference (filed 1993) is similar to the claimed invention in that the technical problem solved is the same, i.e. determining whether the endo-tracheal tube is correctly positioned in a patient. However, in contradistinction to the claimed apparatus in the cited reference correct or incorrect positioning is detected by the use of acoustical waves, i.e. sound, which is used to determine the position of an endo-tracheal tube within the patient. Thus, in the Wodicka reference device acoustical emitters and detectors must be provided in close connection to the inserted tube, cf. Figure 1. This is not the case with the claimed apparatus for detecting the placement of an intubation device in a recipient.

Rather, in the claimed apparatus correct placement of an endo-tracheal tube in a recipient upon ventilation is indicated by a processing unit by detecting whether there is a significant change in the impedance amplitude and the incorrect placement of an endo-tracheal tube in a recipient upon ventilation is indicated by the same processing unit by detecting whether there is a change in the impedance amplitude that is below a specified threshold level, and the claims further require that during use of said apparatus in a recipient that the change in the impedance amplitude is shown on the display or is indicated by the activation of an alarm on the apparatus.

Therefore, in contrast to the cited reference , in the claimed apparatus the indication of placement of an intubation tube in a recipient is shown on a display as a change in measured thoracic impedance as compared to a specified threshold value.

The Pross reference does not cure the deficiencies of the Wodicka reference. The Pross reference, published in 1984 relates to a conventional respiration monitoring system. This device uses electrodes which in use are positioned on the thorax to detect changes in the thorax impedance. Surveillance of the patient is performed by defining and monitoring certain

thresholds of impedance. However, there is absolutely no teaching, suggestion or motivation for the skilled person to apply this teaching for the determining placement of an endo-tracheal tube.

The Examiner alleges that it would be obvious to modify the tube placement apparatus of the Wodicka reference to utilise a thoracic impedance measurement similar to the Pross reference to enable detection of tube placement without invasive means as a substitute to a method based on acoustics. However, this is disputed.

These references are not properly combinable. The Wodicka reference which similarly relates to an apparatus for detecting positioning of an intubation device based upon an acoustical system. By contrast, the secondary reference does not relate to a device for detecting placement of intubation tubes, rather it relates to a conventional respiratory monitoring system. Applicants respectfully submit that one of ordinary skill would not look to such a conventional system for detecting respiration when designing a means for detecting placement of intubation tubes, especially given that the means for detection (electrical impedance) is quite distinct from acoustical detection based methods.

Indeed, if the Examiner's reasoning were valid, then there would have been no reason for Wodicka et al. to instead implement a rather complicated acoustical system given that the respiratory detection system disclosed by Pross was conventional in the art as of the date of the Wodicka invention. By contrast, notwithstanding the fact that the Pross-type respiratory detection device was known and conventional at this time Wodicka instead solved the technical problem by an entirely different and more complex means, i.e. by acoustics. It would seem that if indeed the proposed modification of the Wodicka apparatus were obvious to one of ordinary skill in the art that this problem (detecting placement of an intubation device in a recipient) would not have been effected by this much more cumbersome and inconvenient means.

Stated differently it was not routine to one of ordinary skill as evidenced by the Wodicka et al reference that an already well known technique, i.e. the thorax electrical impedance monitoring, could or should be exploited to monitor placement of the endo-tracheal tube in a recipient. In fact, this rationale is further improper since the references if combined as suggested by the Examiner actually undo or destroy the invention of Wodicka et al (by removing

the acoustic system only to replace it with a distinct detection system. This proposed modification is clearly improper as it goes against the express teachings (and purported advantages) of the Wodicka et al intubation tube detection device.

Based on the foregoing the 103 rejection of claims 1-5, 10-11 and 14-17 based on Wodicka et al. in view of Pross et al should be vacated.

Claims 6 and 7 further stand rejected under 35 USC 103 as assertedly being obvious over the combined teachings of Wodicka et al., Pross et al and further in view of Webber (US2003/0109795). This rejection is also respectfully traversed.

Wodicka et al. and Pross et al. are discussed supra, For the reasons set forth already these references are not properly combined and therefore fail to teach or suggest the claimed apparatus for detecting the placement on intubation tubes in a recipient that detects placement based on electrical impedance values. Webber is cited based on its teaching of the setting of a threshold based on an immediately previous measurement. This is noted, however, Applicants respectfully submit that the rejection is unsustainable as this reference does not bolster the rejection as it similarly provides no incentive for one of ordinary skill to essentially destroy the advantages of the Wodicka acoustic detection device (for detecting placement of intubation tubes) by instead implementing detection of intubation tube placement by detecting electrical impedance, much less suggesting that this modification would be effective.

Based thereon withdrawal of the 103 rejection of claims 6 and 7 based on Wodicka et al., Pross et al., in view of Webber et al. is respectfully requested.

Claim 9 further stands separately rejected under 35 USC 103 as assertedly being obvious over the combined teachings of Wodicka et al. , Pross et al and further in view of Webber (US2003/0109795) and Hharada et al (US Patent No. 5,653,241). This rejection is also respectfully traversed.

Wodicka et al. and Pross et al. and Webber et al. are discussed supra, For the reasons set forth already these references are not properly combined and therefore fail to teach or suggest the

claimed apparatus for detecting the placement on intubation tubes in a recipient that detects placement based on electrical impedance values.

Harada et al. is cited based on its disclosure of a medical device with an on/off switch with a mode for off, a single measurement and a monitoring position. Again it is conceded that this concept is not novel.

However, the teaching of Harada et al. is similarly inadequate to teach or suggest the inventive device for detecting placement of an intubation tube in a recipient since this reference similarly provides no incentive for one of ordinary skill to essentially destroy the advantages of the Wodicka acoustic detection device (for detecting placement of intubation tubes) by instead implementing detection of intubation tube placement by detecting electrical impedance, much less suggesting that this modification would be effective. Also, the reference fails to teach or suggest that the impedance threshold could or should be set at 0.5 ohms. Based thereon withdrawal of the 103 rejection of claim 9 based on the combined teachings of Wodicka et al. , Pross et al and further in view of Webber (US2003/0109795) and Harada et al (US Patent No. 5,653,241) is respectfully requested.

Claim 12 further stands separately rejected under 35 USC 103 as assertedly being obvious over the combined teachings of Wodicka et al. , Pross et al and further in view of Kravet et al. (US2002/0035339). This rejection is respectfully traversed.

Wodicka et al. and Pross et al. are discussed supra, For the reasons set forth already these references are not properly combined and therefore fail to teach or suggest the claimed apparatus for detecting the placement on intubation tubes in a recipient that detects placement based on electrical impedance values. Kravet not cure the deficiencies of these references.

The Kravet is cited based on its disclosure of a medical device with an adjustable threshold that changes based on values input by the user. Again Applicants conceded that this concept is not novel in the context of a medical device.

However, this is irrelevant as the Kravet reference further does not teach or suggest the inventive device for detecting placement of an intubation tube in a recipient since this reference

similarly provides no incentive for one of ordinary skill to essentially destroy the advantages of the Wodicka acoustic detection device (for detecting placement of intubation tubes) by instead implementing detection of intubation tube placement by detecting electrical impedance, much less suggesting that this modification would be effective. Based thereon withdrawal of the 103 rejection of claim 9 based on the combined teachings of Wodicka et al. , Pross et al and further in view of Kravet et al. is respectfully requested.

Finally, Claim 13 stands separately rejected under 35 USC 103 as assertedly being obvious over the combined teachings of Wodicka et al. , Pross et al and further in view of Cantrell et al. (US2001/0011159). This rejection is also respectfully traversed.

Wodicka et al. and Pross et al. are discussed supra, For the reasons set forth already these references are not properly combined and therefore fail to teach or suggest the claimed apparatus for detecting the placement on intubation tubes in a recipient that detects placement based on electrical impedance values. Kravet not cure the deficiencies of these references.

Cantrell is cited based on its disclosure of a medical (defibrillation) device that is for use in conjunction with an endo-tracheal tube. The Examiner alleges that because both devices are used in patients subject to similar problems (cardiac arrest) that it would be obvious to modify the Wodicka intubation tube detection apparatus by use of electrical impedance measurements as taught by Pross et al., in order to integrate the defibrillation device taught by Cantrell et al. with the device of Wodicka et al. as it allegedly would facilitate treatment of a patient undergoing both ventricular fibrillation and being ventilated via an intubation tube.

This rejection is also respectfully traversed. The Cantrell reference similarly provides no incentive for one of ordinary skill to essentially destroy the advantages of the Wodicka acoustic detection device (for detecting placement of intubation tubes) by instead implementing detection of intubation tube placement by detecting electrical impedance, much less suggesting that this modification would be effective or an improvement over the Wodicka acoustic based method of detection.. Based thereon withdrawal of the 103 rejection of claim 13 based on the combined teachings of Wodicka et al., Pross et al and further in view of Cantrell et al. is respectfully requested.

**Conclusive remarks**

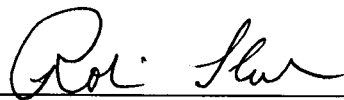
Based on the foregoing, a Notice of Allowance is respectfully solicited. Reconsideration and allowance of all claims are respectfully requested. If any issues remain after consideration of this Response, Examiner Jang is respectfully requested to contact the undersigned by telephone (703-714-7645) so that these issues can be resolved by Examiner's Amendment or a Supplemental Response.

The Commissioner is hereby authorized to charge Deposit Account No. 50-0206 for the Petition fee. In the event that additional fees are necessary, the Commissioner is hereby authorized to charge our Deposit Account No. 50-0206.

Respectfully submitted,

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